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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,700	01/11/2002	Michael C. Pfeil	DP-307033	2 9813

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EXAMINER

DRODGE, JOSEPH W

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,700

Applicant(s)

PFEIL ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6, 10-12, 14, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fond in view of Cosentino et al patent 4,021,341.

Fond discloses a system for controlling flow in a dialysate circuit that includes a first flow path from a dialysis fluid source to the dialysate side of a kidney dialysis machine [as in

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claims 9, 10, 19 and 20], the latter being a second source for a second flow path away from the machine (see figure 1 and column 1, lines 64-67). Also disclosed are first and second flow meter transducers that monitor flow rate properties [as in claims 1-3, 6, 9, 11-13, 16 and 17] that are initially uncalibrated. Fond also discloses starting flow through a bypass interconnection path and stopping flow to and from the second low source by control of respective pumps and valves, afterwards which the flow rate through the flow paths is matched and the transducers are calibrated (column 4, lines 14-38) and finally, disconnecting of the interconnection to restart the flow from the second fluid source and later obtaining readings from the flow meter transducers during dialysis session operation (column 7, lines 59-61).

The claims differ in requiring that flow rates in the flow paths be controlled so as to match each other, utilizing data obtained from both the transducer readings during connection of the bypass path and transducer readings following reconnection of the second fluid source. However, Consentino et al teach such flow matching (column 1, line 20-column 2, line 7; column 4, lines 49-51 and column 5, lines 12-25). It would have been obvious to one of ordinary skill in the art to have modified the Fond method and apparatus by providing means of such control of the flow matching, as suggested by Consentino et al, to stabilize the ultrafiltration or dialysis rate of the blood being purified.

Claims 3, 7, 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fond in view of Cosentino et al as applied to claims 1 and 11 above, and further in view of Lichtenstein patent 4,370,983.

These claims further differ in requiring the transducers to measure the flow rate by sensing differential pressure. Lichtenstein teaches controlled flow through the inlet and outlet lines of a dialysate flow circuit controlled by monitoring of flow rates (column 13, lines 38-column 14, line 17) with such differential pressure sensing (column 10, lines 50-61). It would have been further obvious to one of ordinary skill in the art to have provided flow meter transducers of the type which sense differential pressure, as taught by Lichtenstein, so as to provide increased accuracy of the monitoring of the flow rate properties, by accounting for flow resistances.

Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fond in view of Consentino et al as applied to claims 1 and 11 above, and further in view of Kolberg patent 4,132,644.

These claims further differ in requiring that the pumps be of the peristaltic variety. Kolberg teaches to recirculate dialysate fluid to and from a kidney dialysis machine using a bypass interconnection and using peristaltic pumps. It would have been further obvious to one of ordinary skill in the art to have modified the Fond system by employing peristaltic pumps, as taught by Kolberg, since such pumps are easily controlled, and minimize the need for sterilization and ensuing down time in the kidney dialysis system.

Claims 8, 9, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fond in view of Cosentino et al and Kolberg as applied to claims 5 and 15 above, and further in view of Lichtenstein.

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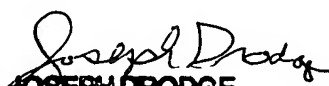
These claims also differ in requiring flow meter transducers to sense differential pressure (see above rejection of claims 3, 7, 13 and 17). It would have been further obvious to one of ordinary skill in the art to have provided flow meter transducers which sense differential pressure in the modified Fond method and apparatus, as suggested by Lichtenstein, so as to measure flow while accounting for flow resistances.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Finlayson patent 5,975,353; Reynal et al patent 5,455,781 and Goux et al are made of record in view of their being of record in related application 10/045,776, these patents generally relating to flow matching and Goux et al further teaching control of flow rates of dialysis fluid in a kidney dialysis system.

Any inquiry concerning this application from the examiner should be directed to Joseph W. Drodge at (703) 308-0403 during the hours of 8:30 to 5:00 on Monday through Friday.

JWD

August 4, 2003


JOSEPH DRODGE
PRIMARY EXAMINER